510K Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR 807-92(c).

1. The submitter of this pre-market notification is:

Mary Kruitwagen
Philips Medical Systems
3000 Minuteman Road
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United States

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AUG 1 2 2013

This summary was prepared on April 10, 2013.

2. a) The name of the subject device is Philips SureSigns Central

b) The trade name of the device is Philips SureSigns Central.

c) The common usual name is central station

4) The Classification names are as follows:

Device Panel	Classification	ProCode	Description
Cardiovascular	870.1025, II	74 MHX	Monitor, Physiological, Patient (With Arrhythmia Detection Or Alarms)
	870.2300, II	74 MSX	System, Network and Communication, Physiological Monitors
	870.1100, II	74 DSJ	Alarm, Blood Pressure
	870.2340, II	74 DPS	Electrocardiograph
	870.2810, I	74 DSF	Recorder, Paper Chart
General Hospital	Not classified	NSX	Software, transmission and storage, patient data

3. The subject device Philips SureSigns Central is substantially equivalent to previously cleared Philips devices, SureSigns VSV cleared under K070588 and Philips IntelliVue Information Center station M3290A rel L.0 cleared under K081983,

M3290B Philips IntelliVue Information Center iX Software rel A.0 under K102495 and Hewlett-Packard 78560 Central Station Patient Information System under K852514.

4. The purpose of this submission is to receive clearance to market a new model central station called the Philips SureSigns Central, model S863291. This is a medical device software product that runs on a PC platform including a proprietary license key (ITE equipment).

5. The subject device Philips SureSigns Central has a modified intended use as that of the legally marketed predicate devices, the Philips SureSigns VSV, the Philips IntelliVue Information Center (PIIC) M3290A and M3290B and the Hewlett-Packard 78560 Central Station Patient Information System.

6. The subject device Philips SureSigns Central has similar fundamental technological characteristics as the legally marketed predicate devices. The subject device has the same safety and effectiveness as the predicate devices.
    a) Philips IntelliVue Information Center iX (PIIC) M3290B with regards to the operating system, the qualified ITE equipment to run the subject software.
    b) Philips SureSigns VSV with regards to compatible patient monitors, physiological measurements received and processed, alarm handling and icon usage. The user interface is the similar for the same functionality.
    c) Philips IntelliVue Information Center (PIIC) M3290A with regards to the functions of retrospective review data, electronic calipers, admit and discharge, remote NBP start/stop
    d) Hewlett-Packard 78560 Central Station Patient Information System with regards to the multi-page monitoring (called overview on the predicate device)

7. Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the subject device. Testing involved system level tests, performance tests, and safety testing from hazard analysis. Pass/Fail criteria were based on the specifications cleared for the subject device and test results showed substantial equivalence. The results demonstrate that the Philips SureSigns Central meets reliability requirements and performance claims and supports a determination of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

August 12, 2013

Philips Medical Systems
c/o Ms. Mary Kruitwagen
Regulatory Engineer
3000 Minuteman Rd
Andover, MA 01810 US

Re: K131032
Trade/Device Name: Philips SureSigns Central
Regulation Number: 21 CFR 870.1025
Regulation Name: Patient Physiological Monitor (With Arrhythmia Detection Or Alarms)
Regulatory Class: Class II
Product Code: MHX
Dated: July 8, 2013
Received: July 9, 2013

Dear Ms. Mary Kruitwagen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, Misbranding by reference to premarket notification (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htmfor the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, Ph.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

K131032

Intended Use

510 (k) Number (if known): _____

Device Name: Philips SureSigns Central (model number: S863291)

Intended Use

The Philips SureSigns Central is intended for central viewing of physiologic waves, parameters and trends from other networked medical devices (patient monitors and vital signs monitors) for multiple patients. It provides secondary operator notification of alarms from other networked medical devices. It provides for the retrospective review of alarm conditions, physiologic waveforms and parameters from multiple patients. The intended use of the printer, when present, is to provide hardcopy text, graphics and waveform data .The Philips SureSigns Central may provide for connection and information exchange to external systems. The Philips SureSigns Central is intended for use in hospitals and out-of-hospital patient care settings (such as clinics, outpatient surgery facilities, long-term care facilities and physician offices) in which care is administered by healthcare professionals.

Prescription Use: ___YES_____ AND/OR over-the-counter Use: ___NO___
(Part 21 CFFR 801 Subpart D) (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by
Owen P. Faris -S
Date: 2013.08.12
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